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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,730	03/11/2004	Chen Su	10209.478	4985

7590 07/31/2006

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,730	SU ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) *4-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/10/06 has been entered.

Claims 1-6 are pending in the application.

Claims 4-6 were withdrawn from the merits as they are directed toward a non-elected invention.

Claims 1-3 were examined on their merits.

Applicant's arguments pertaining solely to the previous rejection are moot in light of the removal of that rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bain(1999) in view of Moniz (US 5,288,491) *or* Bain (1999) in view of Gagnon (1997).

Bain(1999) in view of Moniz (US 5,288,491):

According to Bain, reporting for the Toronto Star, *Morinda citrifolia*, also known as 'noni' juice, was sold as a reconstituted puree juice mixed with blueberry and grape juice (see page 2). This beverage was consumed by many people, as evidenced by the reference (see page 2 for example) as well as by the $40,000 in sales in one month (see page 1).

Bain did not specifically teach wherein the *Morinda citrifolia* was taken on an empty stomach.

Moniz, speaking of the medicinal qualities of *Morinda citrifolia* juice stated:

> Heinicke concludes that "since noni is a potential source of this alkaloid, noni juice can be a valuable herbal remedy. There are some practical problems, however, in using noni juice as a medicine or tonic . . . the flavor of the juice made from ripe Hawaiian noni is terrible (and) another critical problem is (when to use) noni juice as a medicine. If the juice is drunk on a full stomach, it will have very little beneficial action. The pepsin and acid in

> the stomach will destroy the enzyme which liberates xeronine. For a seriously sick person taking the juice on an empty stomach rarely poses a problem . . . however, for the average person . . . timing is critical. It is recommended taking 100 ml. (roughly 3 to 4 fluid ounces) of noni juice a half hour before breakfast." Noni juice should not be taken with coffee, tobacco or alcohol and It would be preferred to use only the green fruit as it has more of the potentially valuable components and less of the undesirable flavor. ('this alkaloid' is refering to xeronine) (col.3, lines 19-56).

Thus, one of ordinary skill in the art would have been motivated to ingest noni juice on an empty stomach in order to gain the benefits of the active ingredient, xeronine in the noni fruit according to Moniz.

Bain (1999) in view of Gagnon (1997):

According to Bain, reporting for the Toronto Star, *Morinda citrifolia*, also known as 'noni' juice, was sold as a reconstituted puree juice mixed with blueberry and grape juice (see page 2). This beverage was consumed by many people, as evidenced by the reference (see page 2 for example) as well as by the $40,000 in sales in one month (see page 1).

Bain did not specifically teach wherein the *Morinda citrifolia* was taken on an empty stomach.

Gagnon (1997) suggested '...taking extracts between meals, apart from food, because that is when they are more easily absorbed by the body. This way ,extracts enter the bloodstream readily and immediately start the healing process' (p.27).

The ordinary artisan would have been motivated to ingest the noni juice on an empty stomach in order to have allowed the juice to be absorbed by the body more readily, thereby obtaining the maximum medicinal benefit of the juice.

Consumption of the product would have intrinsically produced inhibition of PDE because the claims are directed toward simple ingestion of the material which was already known in the art. Thus, the act of ingesting even a minute amount noni juice concentrate would have inherently manifested inhibition of PDE enzyme, especially since PDE enzyme is an endogenous enzyme to humans and especially lacking evidence to the contrary.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

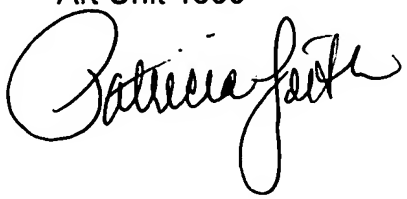
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655



July 23, 2006